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10/601,277	06/20/2003	George E. Barringer JR.	3551.1002-000	6447

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HAMILTON, BROOK, SMITH & REYNOLDS, P.C.  
530 VIRGINIA ROAD  
P.O. BOX 9133  
CONCORD, MA 01742-9133

EXAMINER

RAMILLANO, LORE JANET

ART UNIT	PAPER NUMBER
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1743

MAIL DATE	DELIVERY MODE
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08/09/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

10/601,277

Applicant(s)

BARRINGER, GEORGE E.

Examiner

Lore Ramillano

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 08 May 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-71 is/are pending in the application.
- 4a) Of the above claim(s) 1-21, 44-49, 56-67, 70 and 71 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 22-43, 50-55, 68 and 69 is/are rejected.
- 7) ☒ Claim(s) 25-43 and 51-55 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 23 April 2004 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 11/3/03, 11/19/04, 1/21/05
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- ☐ Notice of Informal Patent Application
- ☐ Other: \_\_\_\_\_

## DETAILED ACTION

### *Election/Restrictions*

1. Applicant's election without traverse of Group I, claims 22-43, 50-55, and 68-69, in the reply filed on 5/8/07 is acknowledged.
2. Claims 1-21, 44-49, 56-67, and 70-71 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 5/8/07.

### *Information Disclosure Statement*

3. The information disclosure statements (IDS) submitted on 11/3/03, 11/19/04, 1/21/05 were considered by the examiner.

### *Drawings*

4. The informal drawing of figure 10 is not of sufficient quality to permit examination. Accordingly, replacement drawing sheet(s) of figure 10 in compliance with 37 CFR 1.121(d) is required in reply to this Office action. The replacement sheet(s) should be labeled "Replacement Sheet" in the page header (as per 37 CFR 1.84(c)) so as not to obstruct any portion of the drawing figures. If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action.

Applicant is given a TWO MONTH time period to submit new drawings in compliance with 37 CFR 1.81. Extensions of time may be obtained under the provisions of 37 CFR 1.136(a). Failure to timely submit replacement drawing sheets will result in ABANDONMENT of the application.

***Claim Objections***

5. Claims 25-43 and 51-55 are objected to because of the following informalities: claim 42 improperly depends on claim 42; claim 42 improperly depends on claim 43; claim 51 improperly depends on claim 51; claim 52 improperly depends on claim 52; claim 53 improperly depends on claim 53; claim 54 improperly depends on claim 54; and claim 55 improperly depends on claim 55. For examination purposes, examiner will interpret claims 42 and 43 to depend on claim 22; and claims 51, 52, 53, 54, and 55 to depend on claim 50. Applicant should further renumber dependent claims 25-41 because it does not seem clear how these claims further limit claim 24.

***Claim Rejections - 35 USC § 102***

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

7. **Claims 22-31, 35, 41-43, 50-54, and 68-69** are rejected under 35 U.S.C. 102(e) as being anticipated by Burshteyn et al. ("Burshteyn," US Pub. No. 2002/0123154).

Burshteyn teaches a method for preparing a macromolecule sample, comprising: automatically acquiring a liquid mixture, the mixture comprising a macromolecule, one or more rough components that are larger than the macromolecule, and one or more fine components that are smaller than the macromolecule; and automatically separating from the macromolecule at

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least a portion of the components by applying the mixture to each of a plurality of filters, with a pressure differential across each filter, the filters comprising a rough filter selected to separate at least a portion of the rough components and a fine filter selected to separate at least a portion of the fine components. (i.e. [0009]-[0015], [0054]).

Burshteyn further teaches the following: a macromolecule that has a molecular weight between about 1,000 and about 200,000 AMU (i.e. [0035]); fine components comprising salt components (i.e. [0038]); automatically reducing the concentration of the salt components by at least 50% (i.e. [0013]-[0015]); automatically increasing the macromolecule concentration by at least 100% (i.e. [0013]-[0015]); automatically reducing the concentration of the salt components by at least 50% (i.e. [0013]-[0015]); automatically reducing the concentration of the salt components by at least 75% (i.e. [0013]-[0015]); automatically increasing the macromolecule concentration by at least 200% (i.e. [0013]-[0015]); automatically controlling the concentration of ions in the mixture by sensing the ion concentration and adding an ion buffer (i.e. [0059]); and automatically directing a desalination buffer (i.e. 49, fig. 1, [0045]) through the fine filter into the mixture.

Burshteyn further teaches automatically lysing the cells in the liquid mixture by adding a lysis buffer to the cells (i.e. [0051]); selecting the fine filter to separate fine components that have a molecular weight less than about 90% of the molecular weight of the macromolecule (i.e. p. 18, claim 30(a)); automatically combining the macromolecule with a denaturation agent (i.e. [0048]); and separating the macromolecule from at least a portion of insoluble lysed cell fragments by automatically applying the mixture to a lysis filter with a pressure differential across the filter (i.e. [0039]).

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***Claim Rejections - 35 USC § 103***

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

10. **Claims 32-34** are rejected under 35 U.S.C. 103(a) as being unpatentable over Burshteyn.

The teachings of Burshteyn are indicated above. Burshteyn does not specifically teach controlling the concentration of hydrogen ion to be in a pH range from 6 to 8. It would have been obvious to a person of ordinary skill in the art for Burshteyn to add a sufficient amount of buffer to the mixture in order to have a pH in the range from 6 to 8 since keeping the blood sample at a neutral pH range will minimize components of the blood sample from degrading.

Furthermore, Burshteyn does not specifically teach selecting the rough filter to separate rough components that have a molecular weight greater than about 110% of the molecular weight of the macromolecule. It would have been obvious to a person of ordinary skill in the art for Burshteyn to have a filter that separates rough components that have a molecular weight

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greater than about 110% of the molecular weight of the macromolecule because it would be desirable to have an additional means for removing the undesirable cellular components from the blood mixture.

11. **Claim 36** are rejected under 35 U.S.C. 103(a) as being unpatentable over Burshteyn in view of Holmes (US 4830969).

The teachings of Burshteyn are indicated above. Burshteyn does not specifically teach utilizing sodium dodecyl sulfate as a denaturation agent.

Holmes teaches a process comprising heating cellular materials in a solution of lysing agent to lyse the desired cells and to agglomerate water soluble nitrogen containing compounds (abstract). Holmes further teaches utilizing sodium dodecyl sulfate as a denaturation agent (i.e. column 5, lines 38-54). It would have been obvious to a person of ordinary skill in the art to modify Burshteyn's method by specifically utilizing sodium dodecyl sulfate as a denaturation agent because it is well known type of agent used for isolating, for example, nucleic acids from biological samples.

12. **Claims 37-40 and 55** are rejected under 35 U.S.C. 103(a) as being unpatentable over Burshteyn in view of Schnipelsky et al. ("Schnipelsky," US 6645758).

The teachings of Burshteyn are indicated above. Burshteyn does not specifically teach heating the macromolecule between from 70 degrees Celsius to about 100 degrees Celsius for about 60 to about 600 seconds.

Schnipelsky teaches a DNA extraction protocol comprising: denaturing a sample by utilizing surfactants and heating a macromolecule between from 70 degrees Celsius to about 100 degrees Celsius for about 60 to about 600 seconds (i.e. column 17, lines 23-38). It would have


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been obvious to a person of ordinary skill in the art to modify Burshteyn's method by incorporating a heating step, as taught by Schnipelsky, because heating samples to denature cellular components is a well known and commonly used technique that involves minimal costs.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lore Ramillano whose telephone number is (571) 272-7420. The examiner can normally be reached on Mon. to Fri. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on (571) 272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Lore Ramillano  
Examiner  
Art Unit 1743

  
Jill Warden  
Supervisory Patent Examiner  
Technology Center 1700